PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 5/00, 5/32

A1

(11) International Publication Number: **WO 00/27450**

(43) International Publication Date: 18 May 2000 (18.05.00)

(21) International Application Number: PCT/US99/26208

(22) International Filing Date: 5 November 1999 (05.11.99)

(30) Priority Data:
60/107,422 6 November 1998 (06.11.98) US

(71) Applicant *(for all designated States except US)*: MDC INVESTMENT HOLDINGS, INC. [US/US]; Suite 200, 900 Market Street, Wilmington, DE 19801 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: HALSETH, Thor [US/US]; 367 Buckboard Circle, Simi Valley, CA 93065 (US). BOTICH, Michael [US/US]; 2330 Eagle Creek Lane, Oxnard, CA 93030 (US).

(74) Agent: ELAND, Stephen; Dann, Dorfman, Herrell & Skillman, Suite 720, 1601 Market Street, Philadelphia, PA 19103 (US).

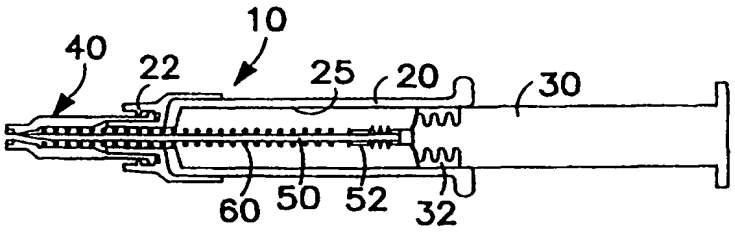
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PRE-FILLED RETRACTABLE NEEDLE INJECTION DEVICE

(57) Abstract

A safety needle-bearing medical device (10) is provided. After use the needle (50) is retracted into the housing (20) of the device to prevent inadvertent contact with the contaminated needle. The invention provides a syringe having a retractable needle. At the end of the injection stroke, the plunger (30) engages a needle retainer that releasably retains the needle. The needle (50) is then released, and a biasing element (60) biases the needle rearwardly. In a preferred embodiment, the needle retainer comprises an adhesive (65) having sufficient strength to retain the needle (50) against the bias of the biasing element (60) prior to actuation of retraction. In addition, the bond of the adhesive (65) is sufficiently fracturable to allow release of the needle upon application of the actuation forced by the plunger (30).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

PRE-FILLED RETRACTABLE NEEDLE INJECTION DEVICE

Field of the Invention

The present invention relates to syringes for administering injections of medicinal fluids to patients. More specifically, the invention relates to such devices having a retractable needle feature for rendering the device non-reusable and safely disposable.

Background of the Invention

Various types of medical devices employ a needle for piercing the skin of a patient for diagnostic or therapeutic purposes. One such device is a hypodermic syringe. Handling of such needle-bearing medical devices after the needle is withdrawn from the patient can result in transmission of various pathogens, most notably human immune virus (HIV), to uninfected medical personnel, due to an inadvertent needle stick. Accordingly, it is desirable to provide a device for injecting medication, wherein the injection needle is retracted into the housing of the device after use.

Description of the Drawings

All of the objects of the present invention are more fully set forth hereinafter with reference to the accompanying drawings, wherein:

Fig. 1a is a side view of a hypodermic syringe having a retractable needle, illustrated prior to use;

Fig. 1b is a side view of the syringe illustrated in Fig. 1a, illustrating the device just prior to retraction of the needle;

Fig. 1c is a side view of the syringe illustrated in Fig. 1a, illustrating the device after the needle has been retracted;

Fig. 2a is an enlarged fragmentary view of the

syringe illustrated in Fig. 1a;

Fig. 2b is an enlarged fragmentary view of the syringe illustrated in Fig. 1b;

Fig. 2c is an enlarged fragmentary view of the syringe illustrated in Fig. 1c;

Fig. 3 is an enlarged view of a needle assembly of the syringe illustrated in Fig. 1a;

Fig. 4a is a side view of a second embodiment of a hypodermic syringe having a retractable needle, illustrated prior to use;

Fig. 4b is a side view of the syringe illustrated in Fig. 4a, illustrating the device just prior to retraction of the needle;

Fig. 4c is a side view of the syringe illustrated in Fig. 4a, illustrating the device after the needle has been retracted;

Fig. 5a is an enlarged fragmentary view of the syringe illustrated in Fig. 4a;

Fig. 5b is an enlarged fragmentary view of the syringe illustrated in Fig. 4b;

Fig. 5c is an enlarged fragmentary view of the syringe illustrated in Fig. 4c;

Fig. 6a is a side view of a third embodiment of a hypodermic syringe having a retractable needle, illustrated prior to use;

Fig. 6b is a side view of the syringe illustrated in Fig. 6a, illustrating the device just prior to retraction of the needle; and

Fig. 6c is a side view of the syringe illustrated in Fig. 6a, illustrating the device after the needle has been retracted.

Detailed Description of the Preferred Embodiments

Referring now to Figs 1a-3, and to Figs 1a-1c more specifically, a syringe for injecting medicinal

fluid is designated generally 10. The syringe includes a needle assembly 40 mounted on the forward of a barrel 20. A plunger 30 is slidably displaceable within the barrel. Displacing the plunger 30 forwardly in the barrel 20 expels the fluid from the syringe 10 into the patient. At the end of the injection stroke, the plunger engages the needle assembly 40 to actuate retraction of the needle. The needle then automatically retracts so that the contaminated needle is enclosed within the housing.

Referring to Fig. 1a, the barrel 20 is generally cylindrical, having a generally closed forward end and a generally open rearward end for receiving the plunger 30. The forward end of the barrel is a fixed generally rigid wall having an opening for receiving the needle. The forward end of the barrel further includes an internally threaded Luer socket 22.

The plunger is slidably displaceable within the barrel. The plunger 30 includes a rubber piston 32 mounted on the forward end of the plunger 30. The piston 32 forms a fluid-tight seal with the interior wall of barrel, so that a fluid cavity 25 is formed within the barrel. The forward end of the barrel forms the forward end of the fluid cavity 25, and the piston forms the rearward end of the fluid cavity.

The needle assembly 40 is attached to the forward end of the barrel 20. Referring to Fig. 3, the details of the needle assembly are shown most clearly. The needle assembly 40 includes a spring housing 42, a needle 50, and a compression spring 50 for retracting the needle. The spring housing is generally cylindrical having a threaded rearward end forming a Luer fitting 44. The Luer fitting 44 cooperates with the Luer socket 22 on the barrel 20 to connect the needle assembly to the barrel.

The sharpened tip of the needle 50 projects

from the spring housing 42 for piercing a patient. A needle hub 52 is attached to the rearward end of the needle 50. The spring 60 bears against the needle hub 52 biasing the needle rearwardly. The needle 50 is releasably attached to the needle housing to retain the needle against the rearward bias of the spring 60. As shown in Fig. 2a, in the present instance, the needle is attached to the needle housing by an adhesive 65.

Referring again to Fig. 1a, the rearward end of the needle projects rearwardly from the spring housing 42 so that when the needle assembly is mounted on the barrel 20 the needle assembly projects into the fluid cavity 25 in the barrel. Specifically, in the present instance, the needle hub 52 project into the fluid cavity.

The needle hub 52 includes a plurality of side ports or openings 55 formed in the rearward end of the needle hub. The openings provide a fluid path for air to prevent air from becoming trapped in the forward end of the fluid cavity 25. The needle hub 52 is disposed so that the opening 55 are aligned with the forward end of the fluid cavity 25.

The needle hub 52 further includes a plurality of sealing ribs 54 that form a fluid tight seal between the needle assembly 40 and the barrel. More particularly, as shown in Fig. 2a, the sealing ribs 54 form a fluid-tight seal between the needle hub 52 and the Luer socket 22. In this way, the sealing ribs 54 provide a fluid-tight seal preventing leakage of fluid from the fluid cavity 25 into the spring housing.

The needle assembly 40 can be attached to the barrel by either the manufacturer or by the user just prior to use. Preferably, the barrel is pre-filled with a measured dose of medicine. Alternatively, medicine can be drawn into the barrel by drawing the plunger rearwardly within the barrel.

Configured in this way, the syringe operates as follows. As shown in Figs. 1a and 2a, prior to injection, the plunger is disposed in the rearward end of the barrel 20 and medicinal fluid is in the fluid cavity 25. The plunger is driven forward in the barrel to inject fluid from the fluid cavity 25 through the needle and into the patient. When the plunger is displaced into the forward end of the barrel, the plunger engages the rearward end of the needle assembly 40, as shown in Figs. 1b and 2b. Specifically, the plunger engages the needle hub 52. Continued forward displacement of the plunger forces the needle forwardly, fracturing the bond between the spring housing and the needle. The spring then propels the needle rearwardly into the barrel so that the sharpened tip of the needle is withdrawn into the syringe, as shown in Figs. 1c and 2c.

Since the plunger abuts the needle 50, the spring drives the needle and the plunger rearwardly. Accordingly, the spring force is sufficient to overcome the friction between the piston 32 and the inside wall of the barrel 20. At the same time, the adhesive bond between the spring housing 42 and the needle is sufficient to retain the needle against the rearward bias of the spring, while providing a readily fracturable interface so that the force required to actuate retraction is not significant. In the present instance, the glue bond fractures upon application of approximately 4-6 pounds of force on the plunger. In addition, the spring housing is formed of plastic and the needle is formed of stainless steel, and preferably the adhesive bonds more strongly with plastic than with stainless steel. In this way, the adhesive will fracture at the interface with the needle rather than at the interface with the needle housing. Therefore, the amount of residual adhesive on the needle after being released is

minimal so that the residual adhesive is unlikely to interfere with the opening at the forward end of the barrel during retraction. Preferably, the adhesive is a UV light curing adhesive such as LOCTITE brand Series 3001 adhesive. The spring provides approximately ½ to 3/4 pounds of force to retract the needle and the plunger.

As the spring 60 propels the needle 50 and the plunger 30 rearwardly, the spring expands so that the needle projects into the fluid cavity 25 in the barrel 20. Accordingly, the opening in the forward end of the barrel 20 is sized to permit both the spring 60 and the needle 50 to pass through the opening.

Referring now to Figs. 4a-c and 5a-c, a second embodiment of a syringe designated generally 110 is illustrated. The syringe 110 operates similarly to first embodiment illustrated in Figs 1a-3 and described above. Accordingly, elements in the second embodiment that are similar to elements in the first embodiment are designated with like reference numerals, with the addition of 100s thereto.

The syringe 110 includes a barrel 120 a plunger 130 and a needle assembly 140 attached to the forward end of the barrel. The forward end of the barrel 120 has a Luer socket 122 for receiving the needle assembly 140. In addition, the forward end of the barrel is generally closed, having a reduced diameter opening sized to receive the rearward end of the needle 150.

As shown in Figs. 4a and 5a, prior to use, the needle assembly 140 retains the needle 150 so that the rearward end of the needle projects into the barrel 120 into a fluid cavity 125 in the barrel 120 formed between the forward end of the plunger 130 and the forward end of the barrel. The needle assembly 140 comprises a spring housing 142 and a compression spring 160. The sharpened

tip of the needle projects forwardly from the spring housing 142, and the spring 160 biases the needle 150 rearwardly.

The needle 150 is releasably attached to the spring housing 142 to retain the needle against the bias of the needle. The needle 150 is attached to the spring housing by a retaining disk 145 fixed to the needle. The retaining disk is fixed to the needle by an adhesive similar to the adhesive described above in connection with the first embodiment. The retaining disk is attached to the spring housing by a snap fit. Specifically, a seat for retaining the disk 145 is formed between an annular shoulder and an annular rib formed on the interior wall of the spring housing.

The needle assembly 140 includes a Luer fitting for attaching the needle assembly to the Luer socket 122 on the forward end of the barrel 120. When the needle assembly is attached to the barrel 120, the needle projects rearwardly into the barrel. Preferably, a side port is formed in the rearward end of the needle to provide a fluid passage for air to prevent air from becoming trapped in the forward end of the barrel.

Operation of the syringe 110 is similar to operation of the first embodiment. As shown in Fig. 4a, prior to use, the plunger is disposed in the rearward end of the barrel. Driving the plunger forwardly in the barrel injects fluid from the fluid cavity 125 into the patient. As shown in Figs. 4b and 5b, at the end of the injection stroke of the plunger, the plunger engages the needle and drives the needle forwardly breaking the bond between the disk 145 and the needle to release the needle. The spring then propels the needle and the plunger rearwardly. After retraction, the spring remains enclosed within the spring housing so that the opening at the forward end of the barrel can be reduced to allow

passage of only the needle.

The syringe may include a plunger lock for preventing re-extension of the needle after the needle is retracted. In other words, the plunger can be locked in the extended position after the needle is retracted. For instance, as shown in Figs. 4a-4c the plunger may include an arm 135 or tab biased outwardly that engages the rearward end of the barrel after retraction to prevent re-extension of the needle. Alternatively, the tip of the needle can be bent, thereby causing the tip to skew off-center after the needle is retracted into the barrel. A similar plunger lock can be incorporated into the first embodiment illustrated in Figs. 1a-3.

Referring now to Figs. 6a-c a third embodiment of a syringe designated generally 210 is illustrated. In the third embodiment, the plunger 230 engages the needle 250 and draws the needle into the barrel 220 to retract the needle as described further below.

Referring to Fig. 6a, the barrel 220 has a generally closed forward end. The syringe 210 may be configured so that a needle assembly is threadedly connectable with the forward end of the barrel as described above in connection with the first two embodiments. However, in the present instance, the needle 250 is attached to a reduced diameter tip 222 that is integrally formed with the forward end of the barrel 220. Similarly, the first two embodiments may configured so that the needle is attached to a tip integrally formed with the barrel, rather than utilizing a separable needle assembly.

The tip 222 releasably retains the needle, preferably by an adhesive 265 similar to the adhesive described above in connection with the first embodiment. A needle fitting in the form of a barb 252 is connected to the rearward end of the needle so that the needle

fitting projects into the fluid cavity 225 in the barrel that is between the piston 232 and the forward end of the barrel 220.

The plunger 230 includes a socket 235 for connectably engaging the needle fitting 252. The piston 232 seals the socket 235 prior to use. In addition, a compression spring 260 is disposed about the plunger 230, between the rearward end of the barrel and the rearward end of the plunger.

Prior to use, the spring 260 is in its relaxed or extended state, as shown in Fig. 6a. During use, the user advances the plunger in the barrel 220 to expel medicine from the syringe 210. When the user advances the plunger, the spring compresses, biasing the plunger rearwardly. At the end of the injection stroke, the needle fitting 252 pierces the piston, exposing the socket in the end of the plunger. Upon continued advancement of the plunger, the socket 235 engages the needle fitting 252 so that the needle connects with the plunger. Further advancement of the plunger drives the needle 250 forwardly fracturing the adhesive bond, thereby releasing the needle. When the user releases the plunger the spring 260 propels the plunger 230 and the attached needle 250 rearwardly so that the sharpened tip of the needle is retracted into the barrel.

Claims

1. A medical device comprising:
   a. a barrel having a generally closed forward end;
   b. a plunger slidably disposed within the barrel, the plunger comprising a piston forming a fluid-tight seal with the barrel such that a fluid cavity for receiving medicinal fluid is formed between the forward end of the barrel and the piston;
   c. a needle having a sharpened tip and being operable between a projecting position in which the sharpened tip projects forwardly from the barrel and a retracted position in which the sharpened tip is retracted into the fluid cavity;
   d. a needle retainer operable to releasably retain the needle;
   e. a spring operable to displace the needle and the plunger rearwardly into the retracted position;
   f. wherein forward displacement of the plunger operates to release the needle so that the biasing element can displace the needle rearwardly.

2. The medical device of claim 1 wherein the needle retainer is an adhesive.

3. The medical device of claim 1 comprising a spring housing, wherein the spring is disposed within the spring housing prior to retraction of the needle, and at least a portion of the spring is disposed in the fluid cavity after retraction of the needle.

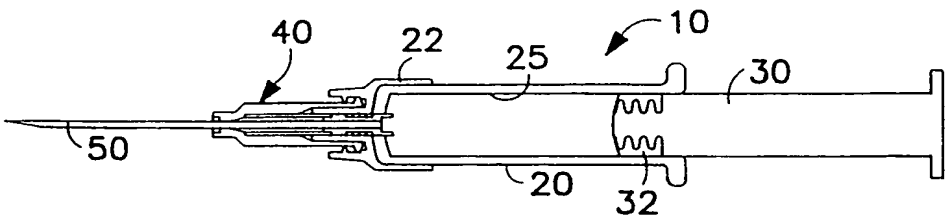


FIG. IA

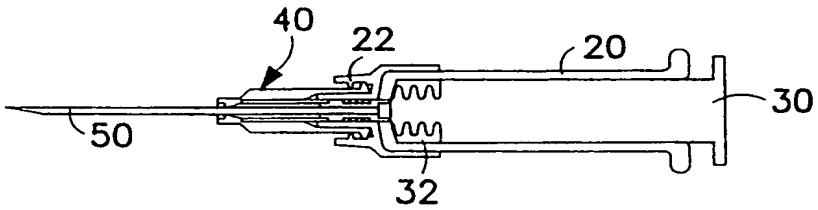


FIG. IB

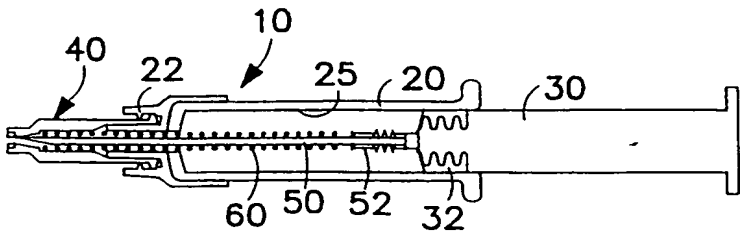


FIG. IC

4. The medical device of claim 1 comprising a plunger lock engaging the barrel to prevent forward displacement of the plunger after the needle is retracted.

5. The medical device of claim 1 wherein the plunger engages the needle.

6. The medical device of claim 1 wherein the plunger is operable to displace the needle forwardly to release the needle from the needle retainer.

7. The medical device of claim 1 comprising a housing, wherein the needle retainer is disposed within the housing and the housing is separable from the barrel.

8. The medical device of claim 7 comprising a seal between the housing and the needle to prevent leakage from the fluid cavity.

9. A medical device comprising:
a hollow housing;
a needle having a sharpened tip;
a biasing element biasing the needle rearwardly
wherein after use of the device the biasing element propels the needle rearwardly so that the sharpened tip is enclosed within the housing.

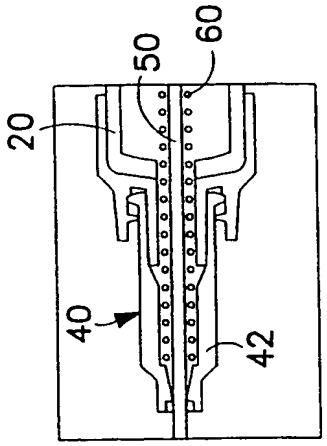


FIG. 2C

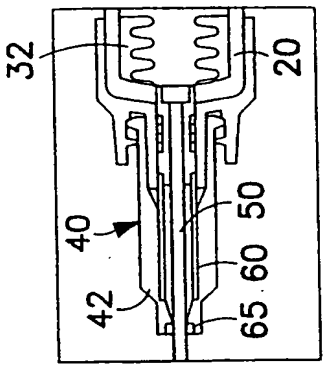


FIG. 2B

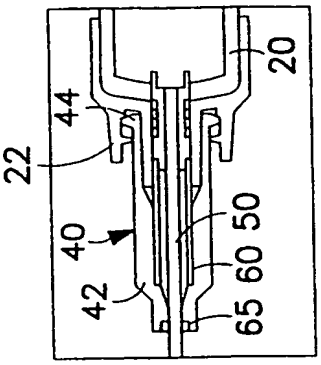


FIG. 2A

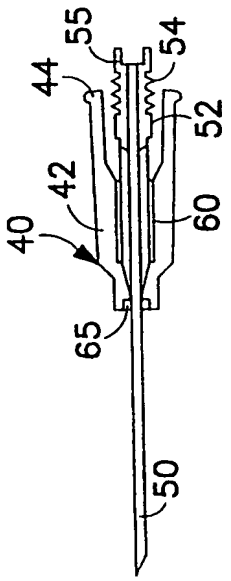


FIG. 3

FIG. 4A

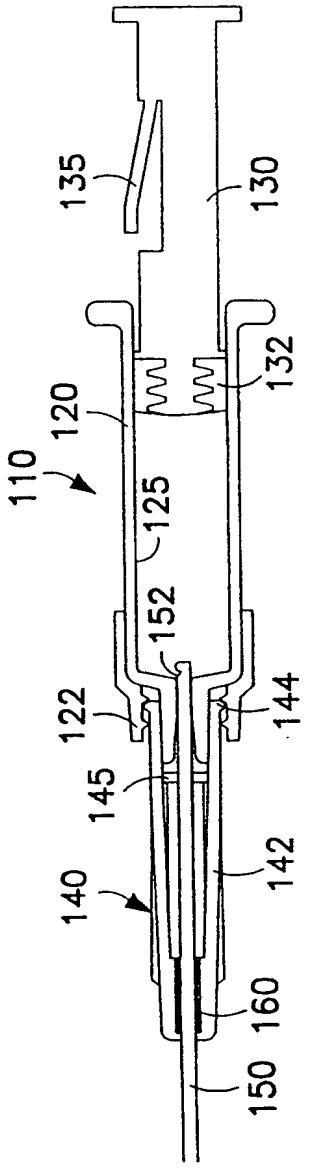


FIG. 4B

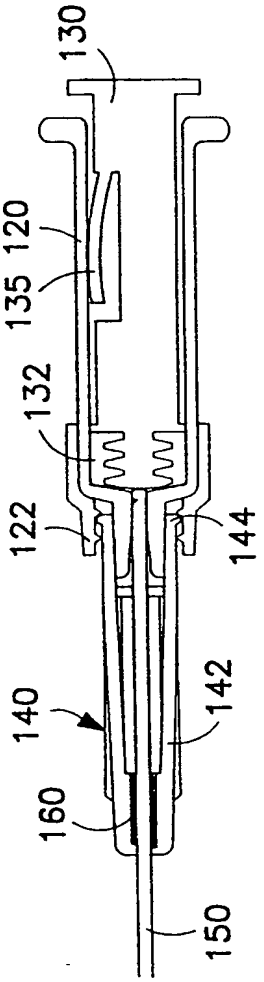
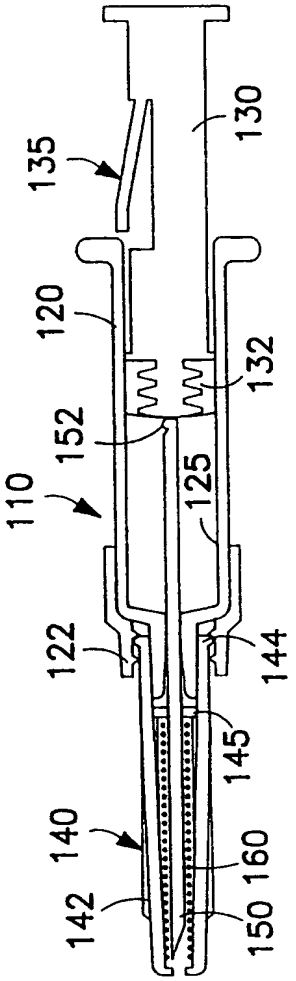


FIG. 4C



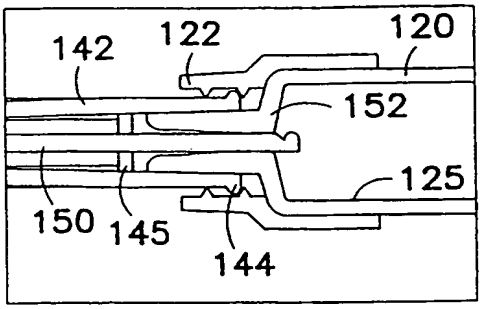


FIG. 5A

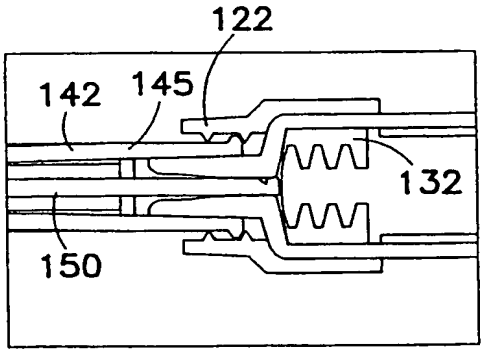


FIG. 5B

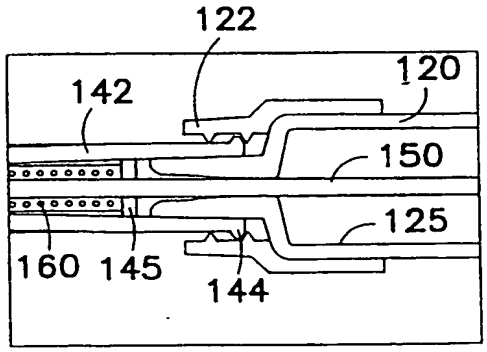


FIG. 5C

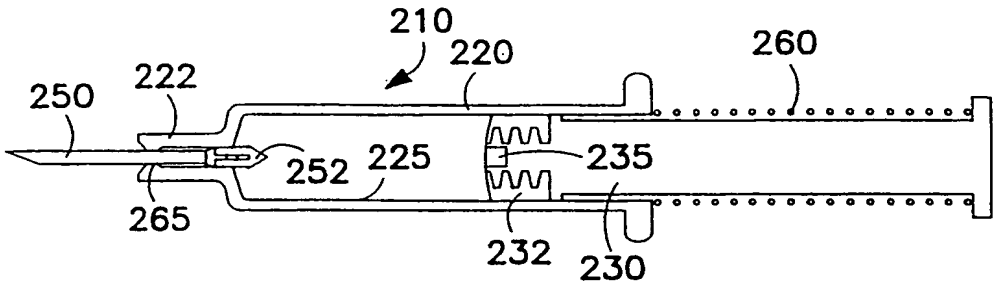


FIG. 6A

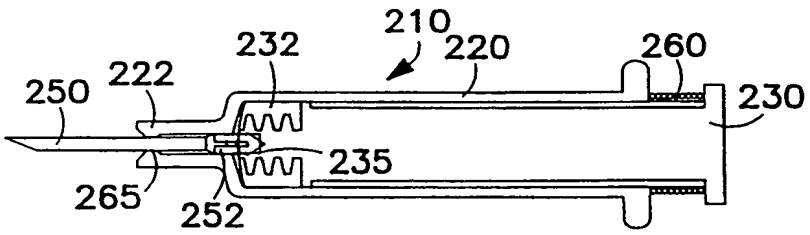


FIG. 6B

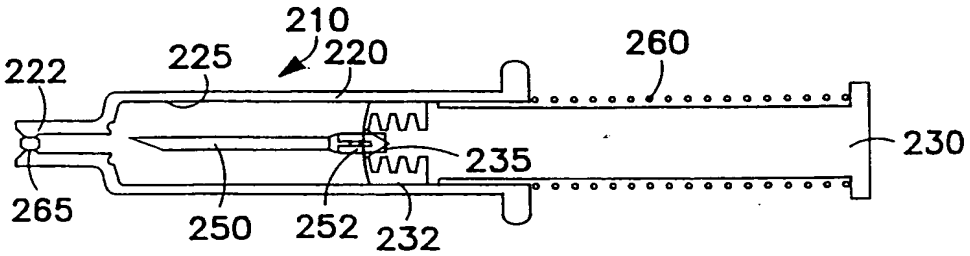


FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26208

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 5/00, 32
US CL :604/110, 195

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110, 192, 195, 208, 213, 240-243

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,973,316 A (DYSARZ) 27 November 1990, entire document.	1-3, 5-9
---		---
Y		4
X	US 5,792,107 A (PETROCELLI) 11 August 1998, entire document.	1-3, 5, 6, 9
X	US 5,487,732 A (JEFFREY) 30 January 1996, entire document.	1-6, 9
---		---
Y		4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 18 FEBRUARY 2000	Date of mailing of the international search report 04 APR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer RONALD STRIGHT, JR. Telephone No. (703) 308-2113

Form PCT/ISA/210 (second sheet)(July 1992)*